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EXAMINER	
FOSTER, CHRISTINE E	
ART UNIT	PAPER NUMBER
1641	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,511	EMMERT-BUCK ET AL.	
	Examiner	Art Unit	
	Christine Foster	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9-26,34 and 35* is/are pending in the application.

4a) Of the above claim(s) *4,6,7,9-11,17,19-25,34 and 35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,12-16,18 and 26* is/are rejected.

7)☒ Claim(s) *1,15 and 16* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 October 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/14/04*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *20070405*.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-7, 9-19, and 26, in the reply filed on 2/20/07 is acknowledged. The elections of "variable region of an antibody binding domain" as the species of targeting moiety; "iodinated tryptophan or tyrosine" as the type of detectable product; of "lactoperoxidase" as the type of active moiety; and of "receptor protein" as the type of target component in the sample are further acknowledged (see the reply at page 8 and the attached interview summary).

2. The Examiner thanks Applicant for pointing out that **claim 26** was incorrectly grouped with Group II in the restriction requirement. As a result of its dependency on claim 1, the claim is properly part of Group I and will be examined below.

3. The traversal is on the ground(s) that as amended, the claims of Groups I and II share the technical feature of "an active moiety which acts within or upon the target cells or components within the sample to generate a detectable signal or product through modification of the target cells or components", and that this technical feature is not taught in the prior art (Reply, page 7).

4. Applicant's arguments are not persuasive because although the claims have been reevaluated in light of the claim amendments made, unity of invention is still found lacking because the technical feature indicated by Applicant does not represent a contribution over the prior art, as detailed in the applied references below. For example, Casciola-Rosen et al. (discussed further in detail below) teaches the technical feature of "an active moiety which acts within or upon the target cells or components within the sample to generate a detectable signal or product through modification of the target cells or components" in that the reference teaches a

DCTA molecule including the active moiety lactoperoxidase, which acts within or upon target cells or components within a liver tissue sample to generate detectable modified products (iodinated proteins) (see especially the abstract and noted passages below).

5. As such, the technical feature of "an active moiety which acts within or upon the target cells or components within the sample to generate a detectable signal or product through modification of the target cells or components" does not represent a *special* technical feature, as it does not make a contribution over the prior art. Accordingly, it is maintained that the claims of Groups I-II do not relate to a single general inventive concept.

6. The requirement is still deemed proper and is therefore made FINAL.

7. Applicant's reply indicates that claims 1-3, 5, 12-19, and 26 read on the elected species. However, the examiner has determined that claims 17 and 19 do not read on the elected species of targeting and active moieties, in that all of the disclosed methods involving amplification as in claim 17 pertain to nucleic acid embodiments, which were not elected for consideration (see withdrawn claims 6-7 and 9-11). Claim 19 does not read on the elected species of targeting moiety since it relates to a generalized targeting moiety as in claim 4, which was not elected for consideration.

Status of the Claims

8. Claims 1-7, 9-26, and 34-35 are pending in the application, with claims 4, 6-7, 9-11, 17, 19-25, and 34-35 currently withdrawn from examination. Claims 1-3, 5, 12-16, 18, and 26 are subject to examination below.

Claim Objections

9. Claims 1 and 15-16 are objected to because of the following informalities:

10. Claim 1 refers to "target cells or components" in lines 5, 6, and 7-8 and to "target**ed** cells or components" in lines 9-10 and 11-12. Since the references appear to refer to the same species, Applicant is requested to employ consistent terminology (i.e., either "target cells" or "targeted cells"). If the references do not in fact refer to the same species, additional clarification is requested.

11. Claim 1 is objected to because it refers to "the DCTA" in line 5, while prior and subsequent references refer to "the DCTA **molecule**".

12. Claims 15-16 are objected to because they refer to "the detectable products", while parent claim 1 refers to "a detectable signal or product". Applicant is requested to employ consistent terminology in order to provide adequate antecedent basis for the limitation of the dependent claims.

Claim Rejections - 35 USC § 112

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claims 1-3, 5, 12-16, 18, and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled

in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

15. Claim 1 as amended recites that the active moiety acts within or upon the target cells or components within the sample to generate a detectable signal or product ***through modification of the target cells or components***. The claim also recites the steps of activating the active moiety, ***thereby producing modified targeted cells or components***, and of detecting the ***modified targeted cells or components***. Claim 26 also refers to detecting ***the modified targeted cells or components***.

Applicant's reply indicates that support for the amendments may be found on page 11, lines 36-38; page 21, lines 1-12; page 22, lines 10-12; page 29, lines 1-10; and on page 34, lines 8-33 (see Reply, page 6).

The disclosure at page 21, lines 1-12 states that the active moiety "acts upon or within the targeted cells to generate a detectable signal", but does not disclose formation of "modified" target cells or components, and does not indicate that the generation of a detectable signal occurs through such modification. Similarly, page 11, lines 36-38 and page 22, lines 10-12 disclose that the active moiety acts on target components or targeted cells, respectively, but do not disclose "modification" of these species. At page 29, lines 1-10 the specification discloses that the active moiety may provide "a distinguishing characteristic to the target component or the cell"; however, such a disclosure cannot be said to have the same meaning as *modifying* the target component or cell. Page 34 discloses automation procedures, but does not describe *modifying* target cells or components.

None of the various passages indicated describe formation of "modified target cells or components". The instant claims now recite limitations that were not clearly disclosed in the specification as filed, and now change the scope of the instant disclosure as-filed.

Although certain disclosed embodiments might arguably be considered to involve "modification" of targeted cells or components (for example, iodination of tryptophan or tyrosine residues by an active moiety that is lactoperoxidase), such species as disclosed are not commensurate with the scope of the claims. Iodination of tryptophan or tyrosine residues by lactoperoxidase fails to convey evidence of possession of the genus of active moieties that generate detectable signals through "modification" of target cells or components, given the sheer number of possible ways in which cells or components may be "modified" by various physical processes or events. For example, various types of "modification" encompassed by the claims would include dyeing, phosphorylation or dephosphorylation, glycosylation, crosslinking, proteolysis, covalent adduction of various chemicals, alteration in the structure or phenotype of cells or components, killing of cells, changes in expression patterns, etc. Such a genus cannot be readily envisaged due not only to the large number of ways in which cells or components may be "modified" but also to the substantial variability among the possible modified forms encompassed by the claims.

Furthermore, with regard to the claimed step of "activating the active moiety of the DCTA molecule, *thereby producing modified targeted cells or components"*, the specification fails to provide adequate written description. The specification generically discloses a step of "activating the active moiety", and further discloses that the active moiety is "capable of generating a detectable signal or product" (see for example page 3, lines 1-9). However, the

specification does not disclose that the activation step *produces modified targeted cells or components*. Just as the claimed genus of "modified" targets cannot be readily envisaged, for the same reasons the steps of activating the active moiety to produce such "modified" targets cannot be envisaged.

In addition, regarding the *active moiety* that acts within or upon the target cells or components to generate a detectable signal or product through "modification" of the target cells or components, the claimed genus is not adequately described by the disclosure of *lactoperoxidase*, since the claims are not commensurate in scope with this limited disclosure. The specification also does not adequately describe the claimed genus of active moieties because there is no disclosure of relevant identifying characteristics or partial structure shared by the members of this genus, nor of any correlation between structure and function (ability to "modify" the targets).

In summary, one skilled in the art cannot envisage possession of the claimed genus of methods involving "modification" of targeted cells or components, based on the disclosure of a single or limited species that may read on the genus (iodination of tryptophan or tyrosine residues by lactoperoxidase active moiety). Since the specification does not clearly introduce the concept of the genus of "modified" components, or of active moieties that generate a detectable signal through "modification" of the target cells or components, one skilled in the art would not envisage possession of all methods involving "modification" of components.

The specification as filed does not provide a written description or set forth the metes and bounds of "modified targeted cells or components". The specification does not provide blaze marks or direction for the instant methods encompassing the above-mentioned limitations as they

are currently recited. Such limitations recited in the present claims, which did not appear in the specification as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112. Applicant is required to cancel the new matter in the response to this Office action. Alternatively, applicant is invited to provide sufficient written support for the limitations indicated above. See MPEP 714.02 and 2163.06.

16. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

17. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

18. Claim 14 recites the limitation "the analyzed products from the sample". There is insufficient antecedent basis for this limitation in the claims.

Claim Rejections - 35 USC § 102

19. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

20. Claims 1-3, 5, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Janeway et al. (Immunobiology: the Immune System in Health and Disease (1999), Elsevier Science Ltd/Garland Publishing, New York, NY, Fourth Edition, pages 50-51).

Janeway et al. teach a method of analyzing tissue sections by immunofluorescence, comprising contacting a DCTA molecule (labeled antibody) with the sample such that the molecule interacts (binds) with at least a portion of the sample (see entire selection, in particular p. 50, section 2-12). The DCTA molecule comprises a targeting moiety (antibody) that is capable of localizing the DCTA to target cells or components in the sample, i.e. those cells that have the corresponding antigen for the antibody (see section 2-12 at pages 50-51, and Figure 2.15 in particular). For example, the reference teaches antibodies that selectively bind to the protein GAD, which selectively binds to the beta cells of pancreatic islets of Langerhans, but not to the alpha cells (see Figure 2.15 and legend). The DCTA molecule further comprises an active moiety (fluorescent dye), which acts within or upon the target cells to produce a detectable signal (fluorescence). The reference teaches activating the fluorescent dye by excitation with light of one wavelength, which causes the dye to emit light of a different wavelength, which is then detected (see especially the paragraph bridging pages 50-51). The target cells bound by the labeled antibody would be considered to be "modified" by this process in that their light absorbing and emitting properties are changed by the presence of the bound labeled antibody. The antibody-bound cells are then detected using a fluorescence microscope.

Alternatively, Janeway et al. teach immunohistochemical techniques, in which an enzyme active moiety is activated by addition of a colorless substrate, which produces a colored reaction product which is then directly observed with a light microscope (see page 51, left column, the first full paragraph).

With regard to claim 3, the targeting moiety comprises a variable region of an antibody-binding domain (see Figure 2.15).

With regard to claim 5, the antigens of Janeway et al. would be considered 'receptor proteins' in the absence of a specific definition for this term in the specification, in that the antigens selectively bind to the antibodies. For example, the GAD protein taught by Janeway et al. (see legend to Figure 2.15) would be considered to be a 'receptor' for the antibody, in that the protein selectively receives and binds to the antibody.

With respect to claim 14, the detectable signal is visualized without physical separation (see especially Figure 2.15).

21. Claims 1-2, 5, 12-13, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Casciola-Rosen et al. ("Lumenal Labeling of Rat Hepatocyte Early Endosomes" *The Journal of Biological Chemistry* (1992) Vol. 267, pages 8213-8221).

Casciola-Rosen et al. teach methods of analyzing liver tissue samples, comprising contacting a DCTA molecule (chemical conjugate of the specific ligand asialoorosomucoid (ASOR) and lactoperoxidase) with the liver samples such that the molecule interacts with the sample (see entire selection, in particular the abstract; p. 8213, right column; p. 8214-8215, "Methods"). The targeting moiety (ASOR) is capable of localizing the DCTA molecule to hepatocyte asialoglycoprotein receptors (ASGP-R); after binding to the receptors, the DCTA molecule is internalized into endosomes of the hepatocytes (see especially the abstract; p. 8213, right column; Figure 1; p. 8215, left column, the first full paragraph; and the paragraph bridging p. 8215-8216). The active moiety (lactoperoxidase) acts on (iodinates) endosome proteins intralumenally (see especially p. 8215, left column, "LPO-mediated Endosome Iodination"). The active moiety is activated by addition of $Na^{125}I$ (ibid) to produce iodinated endosome proteins,

which are then detected by autoradiography (see especially the paragraph bridging p. 8215-8216 and Figure 2). See also p. 8217, right column, to p. 8218; and p. 8219, right column, first paragraph.

With respect to claim 2, the perfused liver systems of Casciola-Rosen et al. would be considered to be "tissue sections", "cytology preparations" as well as "cells *in vitro*" (see p. 8214, left column, "Isolated Perfused Liver System").

With respect to claim 5, as noted above, the ASOR targeting moiety is a specific ligand for ASGP-R receptors (p. 8213, right column, the first full paragraph).

With respect to claim 12, lactoperoxidase catalyzes the iodination of tyrosine residues (p. 8218, left column, first full paragraph).

With respect to claim 15, the iodinated proteins are separated by electrophoresis prior to autoradiography (see in particular p. 8215, "One- and Two-dimensional Gel Electrophoresis"; Figure 6; and the paragraph bridging p. 8215-8216).

Claim Rejections - 35 USC § 103

22. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

23. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

24. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Casciola-Rosen et al. in view of Watts ("*In situ* 125I-labelling of endosome proteins with lactoperoxidase conjugates" *EMBO* Vol. 3 (1984), 1965-1970).

Casciola-Rosen et al. is as discussed above, which teaches a method for analyzing a tissue sample substantially as claimed. However, the reference fails to specifically teach a method in which the detectable signal is visualized without physical separation of the iodinated proteins from the sample.

Watts et al. teach the same DCTA molecule as that employed by Casciola-Rosen et al., namely the ASOR-lactoperoxidase conjugate (see especially the abstract and p. 1964, "Results", the first paragraph). The reference teaches that the ASOR-LPO conjugate can be visualized by cytochemistry of thin sections of material using an electron microscope (see the paragraph bridging p. 1968-1969 and Figure 4 in particular). This procedure is used to reveal which vesicles are iodinated at a morphological level.

Therefore, it would have been obvious to one of ordinary skill in the art to detect the iodinated proteins in the method of Casciola-Rosen et al. by cytochemistry (which does not involve physical separation) as taught by Watts et al. in order to determine which vesicles are iodinated at a morphological level.

25. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Casciola-Rosen et al. in view of Zuerner et al. (US 5,091,301).

Casciola-Rosen et al. is as discussed above, which teaches a method for analyzing a tissue sample substantially as claimed. However, the reference fails to specifically teach a method in which the detectable products (iodinated endosome proteins) are quantified. However, methods for quantifying the results of experiments, and in particular autoradiographic experiments, were routine in the art at the time of the invention.

For example, Zuerner et al. teach that autoradiographic images may be quantitated by scanning the autoradiographs with a laser densitometer (column 10, lines 59-66). This allows for direct comparison among different reactions or samples (column 11, line 67 to column 12, line 3).

Therefore, it would have been obvious to quantify the iodinated proteins in the method of Casciola-Rosen et al., for example by performing densitometric analysis of the autoradiographs as taught by Zuerner et al. One would be motivated to do this in order to express the results of the experiment numerically, which would allow for direct comparison among multiple reactions or samples as well as enable statistical manipulation of the data.

26. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Casciola-Rosen et al., in view of Ohbayashi et al. (US 6,613,564 B2).

Casciola-Rosen et al. is as discussed above, which teaches a method for analyzing a tissue sample substantially as claimed. However, the reference fails to specifically teach a

method in which the targeting moiety and the at least one active moiety are each covalently linked to a *polymer linker.*

Ohbayashi et al. teach conjugates of enzymes and targeting moieties (protein with specific binding potency), in which the enzyme and protein may be each covalently complexed to a carrier such as polylysine (see especially the abstract and column 3, lines 35-59; column 5, line 49 to column 6, line 52). The reference teaches that by conjugating the enzyme to the carrier, and then further conjugating the specific binding protein to the enzyme and/or to the carrier, higher binding capacity and assay sensitivity is possible because many molecules of the protein as well as many molecules of the enzyme can be conjugated to the carrier (see especially column 3, lines 1-65 and column 7, line 59 to column 8, line 37). Possible carriers include the polymer linker poly-L-lysine, which is disclosed in the instant specification as an example of a suitable polymer linker. See column 6, line 47 to column 7, line 58, and the Examples, in particular Example 1, in which the linker is provided by reaction of poly-L-lysine hdyrobromide.

Therefore, it would have been obvious to conjugate the ASOR targeting moiety and the enzyme of Casciola-Rosen et al. to a carrier such as poly-L-lysine, as taught by Ohbayashi et al., in order to allow for multiple enzyme molecules and multiple targeting moieties to be attached to the carrier, thereby increasing the binding capacity of the molecule and allowing for increased sensitivity.

27. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over either Janeway et al. or Casciola-Rosen et al.

The references are as discussed above, which teach methods for analyzing a tissue sample substantially as claimed. However, the references fail to specifically teach a method in which detection of the modified targeted cells or components (iodinated endosome proteins) is "automated".

However, the courts have ruled that broadly providing an automatic or mechanical means to replace a manual activity that accomplishes the same result is not sufficient to distinguish over the prior art. In re Venner, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958). See MPEP 2144.04.

Therefore, it would have been *prima facie* obvious to automate the detection step in the methods of either Janeway et al. or Casciola-Rosen et al. in order to accomplish the same result (detection of the fluorescently labeled or iodinated proteins, respectively). One would be motivated to do this for the well known benefits of automation, for example improving reproducibility, reducing human error, reducing the need for steps to be performed by a technician and thereby saving time, etc.

Double Patenting

28. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

29. Claims 1-3, 5, 12-16, 18, and 26 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-83 of copending Application No. 10/543;218. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application also claims a method comprising the steps of contacting a biological sample (which may be a tissue section, see especially claims 4-6 and 41-42) with a DCTA molecule ("reagent") that comprises a targeting moiety and an active moiety ("activating moiety") so that the DCTA molecule selectively binds to a target within the biological sample (see especially claims 1 and 25-41). The activating moiety of the copending application would have the same noted properties as in the instant claims in that it may catalyze the adherence of the target to a transfer surface (see especially claims 1 and 40), which would be considered to represent a species that anticipates the genus of "modification" of the target as recited in instant claim 1. The activating moiety may also be capable of producing a change in the target in response to a "trigger event" such as electromagnetic radiation (see claims 16-23), which represents a species that anticipates the claimed step of "activating" the active moiety as recited in the instant application. The copending application further claims detecting the modified target, in that the adhered targets may be quantified (see especially claims 46-54). The method may be automated (see claim 55).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Foster whose telephone number is (571) 272-8786. The examiner can normally be reached on M-F 8:30-5. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached at (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CFoster

Christine Foster, Ph.D.
Patent Examiner
Art Unit 1641

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